

#2

**Patent**

Serial No. 085,942 15-P7

Inventor Charles E. Smith

Title High Speed

The following statement is made:

☐ I am the inventor.

☒ Executed Declaration

☐ Unexecuted Declaration

☐ Priority

☒ Claim of Priority

☐ Priority Document

☐ Informal Drawings

☐ Formal Drawings

☐ Assignment

☒ Verified Statement

☒ Information Disclosure

☒ Prior Art

☐ Preliminary Amendments

☐

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**1957**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of )  
CURT I. CIVIN )  
Serial No. 055,942 ) Group Art Unit 128  
Filed: June 1, 1987 )  
For: HUMAN STEM CELLS AND )  
MONOCLONAL ANTIBODIES )

INFORMATION DISCLOSURE STATEMENT

Honorable Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

The following references, which are divided into several categories, are submitted in the subject application.

The enclosed article "Antigenic Analysis of Hematopoiesis III. A Hematopoietic Progenitor Cell Surface Antigen Defined by a Monoclonal Antibody Raised Against KG-1a Cells," by Civin, C.I. (the inventor here), et al J. Immunology 133:157-165 (1984) discloses the monoclonal antibody which recognizes a human hematopoietic progenitor cell surface antigen. The article was published after the filing of the parent application S.N. 670,740.

In addition, the following two abstracts, of which the inventor is an author, are dated more than a year before the subject filing date. They refer to My10 and the monoclonal antibody which recognizes it, but neither enables one without undue experimentation to make the hybridoma that produces the antibody that uniquely recognizes a unique antigen on a stem cell, or the antibody itself. These abstracts do not provide an impetus that would lead one skilled in the art to an antibody to a human pluripotent lympho-hematopoietic stem cell.

Civin, Strauss et al (1982) Blood 60(5):95a (abstract);

Civin, Vaughan et al "Cell Surface Antigens of Human Myeloid Cells," (1982) Exp. Hematol. 10:129 (abstract).

The following articles, of which the inventor is an author, are dated less than one year before the filing of this application.

Civin, Brovall et al (1983) Hybridoma 2:125a, presented Feb. 8, 1983, abstracts available Feb. 6, 1983;

Brovall, Shaper, Civin et al (1983) Exp. Hematol. 11 (Supp.):199, presented July 14, 1983, abstract available July 10, 1983.

Civin, Vaughan et al (1983) Exp. Hematol. 11 (Supp.): 84, presented July 12, 1983, abstract available July 10, 1983;

Strauss & Civin (1983) Exp. Hematol. 11:20 presented July 14, 1983, abstracts available July 10, 1983;

Strauss, LaRusa and Civin (1984) I.S.E.H. Abstract;

Leary, Ogawa, Civin et al (1984) I.S.E.H. Abstract.

A copy of a Declaration of Dr. Civin is submitted herewith. It was originally filed in the parent application S.N. 670,740. It states that Dr. Civin, the applicant, was the sole inventor of the subject matter described in the application.

The following two references teach the use of two antibodies which were speculated to be able to recognize stem cells, RFB-1 and RFB-HLA-DR. However, the Bodger references as well as subsequent experimentation have shown that each of these antibodies also recognizes mature lymphoid and myeloid cells. A copy of a Rule 132 Declaration of the inventor, originally submitted in the parent application S.N. 670,740, is submitted herewith which states that the RFB-1 antibody reacts with many types of mature lymphoid and myeloid cells.

Bodger et al, "Surface Antigenic Determinants on Human Pluripotent and Unipotent Hematopoietic Progenitor Cells", Blood, Vol. 61, pp. 1006-1010 (1983).

Bodger et al, "A Monoclonal Antibody Specific for Immature Hematopoietic Cells and T Lineage Cells", J. Immunology, pp. 2269-2274 (1981).

The Civin, J. Immunology article cites as references the following papers (which we attach for the record) and explains their possible relevance. These have been reviewed and are deemed less relevant than the art cited above.

Nadler et al (1981) Prog. Hematol. 12:187-225;

Reinherz et al (1980) N. Engl. J. Med. 303:370;

Ritz et al (1980) Nature 283:583;

Stashenko et al (1980) J. Immunol. 125:1678.

Monoclonal antibodies which recognize mature T-cells were, of course, also known. Patents which disclose such monoclonal antibodies include:

Reinherz, U.S. Patent 4,443,427;

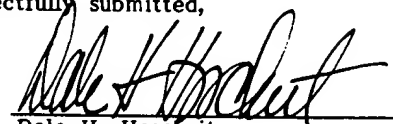
Kung et al, U.S. Patent 4,381,295; and

Bieber et al, U.S. Patent 4,381,292.

Winchester et al (1977) Proc. Nat'l. Acad. Sci. USA, 74: 4012, describes a polyvalent antibody to antigens on B lymphocytes.

Respectfully submitted,

By:



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(202) 296-5500

Dated: July 13, 1987

1107.21635

055,942

LIST OF PRIOR ART CITED BY APPLICANT  
(Use several sheets if necessary)

APPLICANT

CURT I. CIVIN

FILING DATE

June 1, 1987

GROUP

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AA	4 4 4 3 4 2 7		Reinherz			
AB	4 3 8 I 2 9 5		Kung et al			
AC	4 3 8 I 2 9 2		Bieber et al			
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## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

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		Civin Strauss et al (1982) Blood 60(5):95a (abstract)
AS		
AT		Civin, Vaughan et al "Cell Surface Antigens of Human Myeloid Cells", (1982)
		Exp. Hematol. 10:129 (abstract)

EXAMINER

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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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AR	<input checked="" type="checkbox"/>	Winchester et al (1977) <u>Proc. Nat'l. Acad. Sci USA</u> , 74:4012
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